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Remarks

Claims 1-4, 9-16, 18 and 19 were pending in the subject application. By this Amendment, the applicant has amended claims 1 and 4. No new matter has been added by these amendments. Accordingly, claims 1-4, 9-16, 18 and 19 are still before the Examiner for consideration. Favorable consideration is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of applicant's agreement with or acquiescence to, the rejections of record. The applicant expressly reserves the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1-3 and 9-11 are rejected under 35 USC §103(a) as anticipated by Schreck (U.S. Patent No. 4,411,655) in view of Prestidge *et al.* (U.S. Published Application No. 2004/0193109). The applicant respectfully traverses this rejection because the cited references, alone or in combination do not disclose or suggest the unique and advantageous system claimed by the current applicant.

Schreck teaches a needle-cannula combination comprising a tape-wound, helical ribbon (col. 4, lines 18-19) cannula of a shape memory alloy surrounded by an elastomeric sheath (col. 3, line 51-53). In the martensitic alloy phase, usually pre-injection, the cannula is coiled around the needle "so that the overall outer diameter 'G' comprising cannula 4 together with sheath 7 is of such size as to be convenient for introduction into a particular vascular or body compartment." (col. 3, lines 53-57). In the austenitic alloy phase, usually post-injection, increased temperatures cause the helically-wound tape to basically unwind. This provides a larger internal diameter that stretches the outer elastomeric sheath. Further, as Schreck repeatedly states, the increased diameter of the cannula dilates a vascular member facilitating the insertion of a larger diameter needle or catheter into the vascular member (see, for example, col. 2, lines19-20; col. 4, lines 53-54; col. 6, lines 29-50).

Schreck also describes an alternative embodiment comprising a cylinder coiled with unconnected, but overlapping ends (martensite phase) covered with an elastomeric sheath, wherein the cylinder uncoils to a larger diameter (austenite phase) allowing insertion of a larger diameter needle or catheter. (col. 6, lines 59-68) A further alternative embodiment described in Schreck is a cannula comprising a tubular mesh without an elastomeric sheath. (col. 6, line 54-57)

It is apparent that the Schreck devices are not designed to transmit fluids, but only to facilitate introduction of larger bore needles and catheters that are capable of transmitting fluids. In addition, all of the shapes described and shown by Schreck are generally tubular.

The device of the subject invention is specifically designed for the transmission of fluids. It does not require the introduction or utilization of additional devices through its memory lumen to accomplish fluid transmissions. In fact, as recited in claim 1 and unlike Schreck, the subject device is designed to maintain its luminal diameter. The memory specific configurations are intended to reduce or eliminate catheter migration or withdrawal thereby preventing interference in fluid transmissions. For example, claim 1 of the subject invention currently recites catheter configurations including a bolus, helical spiral, pig tail, tennis racquet, halo, mushroom, and sinusoidal wave that are attained after insertion (austenite phase) of the catheter and exposure to tissue environments. Applicant has amended claim 1 to clarify that the devices of the subject invention are capable of transmitting fluids.

The addition of Prestidge *et al.* does not cure the defects of the Schreck disclosure as noted above. Further, the safety features described by Prestidge *et al.* teach away from certain aspects of the subject invention. Specifically, the safety features described in Prestidge *et al.* utilize shape memory alloys (SMA) as a means to control the position of the needle within the needle guard. The SMA needle "movement means comprises a component which is responsive to body heat such that when the needle is inserted into tissue, in use, the movement means is exposed to body temperature and the resulting change in temperature of the movement means causes the needle and the shielding means to be moved relatively automatically to the inoperative position." (page 1, paragraph [0006])

In contrast, the device of the subject invention utilizes a "manual retraction button" (page 6, line 23) in conjunction with a coil spring to control the movement and position of the needle within the housing. For example, the coil spring can be retained within the catheter and compressed between the housing and needle by means of a cantilevered stop that engages with the catheter. A manually operated button affixed to the cantilevered stop is used to disengage the stop from the catheter, permitting the spring to uncoil and extend the needle from the proximal end of the catheter. Unlike Prestidge *et al.* the devices of the subject invention are under complete control of the user and do not automatically deploy the needle.

Claim 4 has also been rejected under 35 U.S.C. §103(a) as being unpatentable over Schreck in view of Prestidge *et al.* and further in view of VanTassel *et al.* (U.S. Patent No. 6,605,061). The applicant respectfully traverses this grounds for rejection because the cited references, alone or in combination do not disclose or suggest the unique and advantageous devices claimed in the subject application.

The Examiner states that Schreck meets the limitations of claim 1, from which claim 4 depends, but does not include a plurality of openings. Applicant respectfully traverses this rejection by stating that, as discussed above, Schreck does not disclose or suggest the system of claim 1, as currently presented. Specifically, Schreck does not teach the use of a shape memory polymer or alloy that assumes the specific shapes recited in the pending claims. Further, Schreck does not teach a device for transmission of fluids. Addition of the VanTassel *et al.* reference does not cure the defects noted with respect to the Schreck disclosure, in fact, the VanTassel *et al.* reference teaches away from the subject invention by stating that the "catheter **20** must be made of a flexible and compliant material capable of bending" (col. 2, line 65-67). Further, the initial shape of the VanTassel *et al.* catheter is maintained by an inflatable balloon, stiffening wires or springs within the catheter that, only upon removal from the lumen of the catheter, allow the catheter to obtain some predetermined shape (col. 3, lines 3-17). This is not the same as utilizing a temperature reactive shape memory alloy or polymer as disclosed in the subject application.

In addition, while VanTassel *et al.* disclose a plurality of openings, the openings are preferably positioned adjacent to tissues, specifically the endocardium. The embodiments disclosed by VanTassel *et al.* are advantageous because they maintain the multiple apertures adjacent or next to the tissues to be treated (col. 3, line 1 and col. 4, lines 15-19).

Alternatively, the subject invention specifically requires at least one, or multiple openings to be clear of obstructions and away from tissues to provide optimal fluid flow and/or exchange within the center of the lumen of the vessel. (page 4, line 10 and page 5, lines 29-30). Claim 4 clearly states that the openings are positioned to "allow for maximum blood flow". Obviously, if the openings are adjacent to tissues as described in VanTassel *et al.*, they would not achieve maximum blood flow.

In view of the above comments, the applicant asserts that a *prima facie* case of obviousness has not been presented with respect to dependent claim 4. Therefore, reconsideration and withdrawal of the rejection of claim 4 under 35 U.S.C. §103(a) is respectfully requested.

Claims 12-16 have been rejected under 35 U.S.C. §103(a) as unpatentable over Schreck, in view of Prestidge *et al.* and further in view of Weikel *et al.* (U.S. Published Applicatoin 2002/0177866). The limitations of the Schreck and Prestidge *et al.* references have been discussed above with respect to the rejection of claim 1, from which claims 12-16 ultimately depend. The Weikel *et al.* reference does not cure the defects noted in the Schreck or Prestidge *et al.* references by the mere recitation of various therapeutic agents or hydrophilic coatings. The skilled artisan would have had no reason to look to the Weikel *et al.* reference for guidance in developing a needle/catheter system wherein the catheter has a first configuration prior to tissue penetration and a second configuration after tissue penetration, wherein the second configuration is of a specific shape useful in maintaining the needle/catheter's position for proper fluid flow during dialysis.

The Schreck, Prestidge *et al.* and Weikel *et al.* references, alone or in combination, do not disclose or suggest the unique and advantageous devices claimed in the subject application. Accordingly, the applicant respectfully submits that a *prima facie* case of obviousness has not been presented with respect to claims 12-16. Therefore, reconsideration and withdrawal of the rejection of claims 12-16 under 35 U.S.C. §103(a) is respectfully requested.

Claims 18 and 19 have been rejected under 35 U.S.C. §103(a) as being obvious over Schreck in view of Prestidge *et al.* and further in view of Sharkey *et al.* (U.S. No. 6,261,311). The applicant respectfully traverses this grounds for rejection because the references, either or alone or in combination, do not describe or suggest the claimed invention. The limitations of the Schreck and Prestidge *et al.* references have been discussed above with respect to the rejection of claim 1, from which claims 18 and 19 depend. The Sharkey *et al.* reference teaches a sheath and catheter combination, where the catheter has visible markings that are detectable through the sheath, which is transparent. The skilled artisan would have had no reason to look to the Sharkey *et al.* reference for guidance in developing a safe needle/catheter system in which the catheter comprises a shape-memory polymer or alloy, where the needle is moveable and the catheter itself is the safety feature preventing any inadvertent needle sticks. Thus, the skilled artisan would not have found in the Sharkey *et al.* reference any remedy to the defects noted in the Schreck and Prestidge *et al.* references. Accordingly, the applicant asserts that a *prima facie* case of obviousness has not been presented with respect to claims 18 and 19. Therefore, reconsideration and withdrawal of the rejection of claims 18 and 19 under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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